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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/596,419

06/13/2006

Ana Maria Castano Mansanet

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PATENT DIVISION

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EXAMINER

CHANDRAKUMAR, NIZAL S

ART UNIT

PAPER NUMBER

1625

NOTIFICATION DATE

DELIVERY MODE

04/10/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@lilly.com

Office Action Summary	Application No. 10/596,419	Applicant(s) CASTANO MANSANET ET AL.	
	Examiner NIZAL S. CHANDRAKUMAR	Art Unit 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 March 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,6,7,9,11,15 and 25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,6,7,9,11,15,25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants response filed 03/04/2008 is acknowledged.

Claims 1, 2, 6, 7, 9, 11, 15, 25 are pending.

Response to Applicant's Remarks:

Claim Rejections - 35 USC § 112

Previously presented rejections under 35 USC § 112 second paragraph are withdrawn in view of Applicants Remarks.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 and dependent claims are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As instantly presented, claim 1, line 4 reads

X represents ~~S or O~~;

However, the applicant remarks indicate that X is S. Amendment consistent with remarks is required.

Claim 2, is redundant since according to present amendments R2 is -CO₂H.

The previously presented rejection of claim 25 is maintained for reasons of record. The amendment is not persuasive.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any

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person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Applicant's arguments and amendments to the claims partially overcome the previously presented rejection under scope of enablement. With regards to potential, intended utility of the compounds of the claims, applicant's arguments are not persuasive. Specifically, applicant states that

The Examiner stated in the Office Action dated December 4, 2007 that Applicants have not provided biological activity. To establish enablement, all that is required is a reasonable correlation between a biological activity and the asserted use. *Nelson v. Bowler*, 626 F.2d 853, 857, 206 USPQ 881, 884 (CCPA 1980). See also MPEP § 2107.03. Applicants have stated in the specification on Page 212, line 2, that "the ability of compounds of Formula I to potentiate glutamate receptor-mediated response can be determined by one of ordinary skill in the art." Applicants then continue on to explain a procedure useful for determining whether compounds potentiate glutamate receptor-mediated responses. This information enables the skilled artisan to determine the ability of compounds of the present invention to potentiate glutamate receptor function. Moreover, the skilled artisan appreciates that compounds potentiate glutamate receptor function are useful in the treatment of a variety of disorders, including the disorders listed on page 20, lines 1-16 of the specification. Applicants are not required to place in the specification that which is well-known in the art. *In re Buchner*, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991). Thus, applicants have provided sufficient guidance and examples in the specification to enable one of ordinary skill in the art to make and use the instantly claimed compounds.

Previous rejection stated the following:

The specification does not provide any biological data for any of the compounds.

With regards to using of the compound, the medicinal chemistry art is unpredictable as to which compound would have the desired biological activity. Further, there is no disclosure in the specification with regards to the pharmacophore needed for the modulation of AMPA receptor activity.

For the above reiterated reasons, the rejection under 35 U.S.C. 112, first paragraph is maintained.

A disclosed property of a chemical compound can fulfill the utility disclosure requirements of 35 USC §112 if persons skilled in the art to which that property pertains could use the compounds without undue experimentation and the compounds are derivatives related in structure and significant properties to a common and well-known family of useful compounds. *In re Folkers et al.* (CCPA 1965) 344 F2d 970, 145 USPQ 390. What is necessary is a disclosure of an activity coupled with knowledge as to the use of that activity. *In re Bundy* (CCPA 1981) 642 F2d 430, 209 USPQ 48. If the disclosed utility is an *in vitro* activity, there must be a reasonable correlation between it and an *in vivo* activity. *Cross et al. v. Iizuka et al.* (CAFC 1985) 753 F2d 1040, 224 USPQ 739.

When the claimed compound belongs to a class of compounds whose members are recognized to be useful for a particular purpose and it is within the skill of the art how to use the claimed compound for that purpose, the requirements of 35 USC §112 are met by a disclosure that the claimed compound is useful for that purpose. *Ex parte Ladd et al.* (POBA 1955) 112 USPQ 337; *In re Hitchings et al.* (CCPA 1965) 342 F2d 80, 144 USPQ 637.

What is found in the specification is disclosure of how to ascertain potential biological activity. This academic teaching is not tantamount to utility disclosure. Neither the applicant nor prior art search reveals whether compounds of the instant formula or related structure would have AMPA receptor activity. Given that assay protocols are available for a variety of receptors including AMPA receptor, simply providing assay procedures for example, opioid receptor activity would not make any disclosed compounds analgesic.

Genentech Inc. v. Novo Nordisk A/S (CA FC) 42 USPQ2d 1001, states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

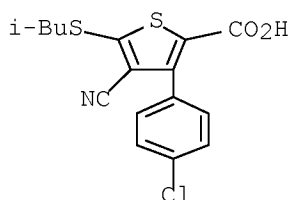
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Applicant amended the claims by removing certain specific elements of the claims to negate the previously presented rejections under 35 U.S.C. 102(b).

As currently amended,

Claim 1 and dependent claims rejected under 35 U.S.C. 102(b) as being anticipated by Selwood et al. (WO 2001032604)

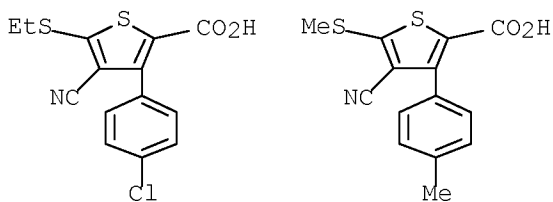
Selwood et al.



corresponding to compounds of the instant formula I.

Claim 1 and dependent claims rejected under 35 U.S.C. 102(b) as being anticipated by Abdulla et al. (EP 273602).

Abdulla et al teach,



corresponding to compounds of the instant formula I.

Prior art not relied upon:

Augustin et al. Tetrahedron (1976), 32(24), 3055-61.

Dehne et al. Pharmazie (1978), 33(10), 687-8.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NIZAL S. CHANDRAKUMAR whose telephone number is (571)272-6202. The examiner can normally be reached on 8.30 AM - 4.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 571 0272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nizal S. Chandrakumar

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/D. Margaret Seaman/
Primary Examiner, Art Unit 1625